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APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/089,894	06/03/98	BOMSHTEYN	A 19603/871 (CR)
			EXAMINER

HM12/0214

PETER ROGALSKYJ
NIXON HARGRAVE DEVANS & DOYLE
CLINTON SQUARE
P O BOX 1051
ROCHESTER NY 14603

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 02/14/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/27/99

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-51 is/are pending in the application.
- ☐ Of the above, claim(s) 49-51 is/are withdrawn from consideration.
- ☒ Claim(s) 1-47 is/are allowed.
- ☐ Claim(s) 48 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

0206

Applicants' election of Group I with traverse is acknowledged. Applicants' traversal is found persuasive in part. Group II is now rejoined with Group I. In addition, Group III is joined in part. In claim 48, there are three structures, the first of which bears variable X and Y¹, the second bears variable A¹, and the third bears variable A². Group III will be joined with Groups I and II only to the extent that the second and third structures (of claim 48) are encompassed. The method of treating cancer using the first structure of claim 48 will also be examined if applicants add the proviso to claim 48 that one of X and Y¹ must be:

“- peptide-NHNNH-CO-antibody-OH “.

Betulonic aldehyde, for example, is a known compound; several references of record have disclosed it.

Applicants may, if deemed appropriate, add a claim which is drawn to a method of treating cancer by administering a compound of claim 1. This will be examined along with the other elected claims.

In accordance with the foregoing, claims 49-51 are withdrawn from consideration. Claims 1-48 are examined in this Office action.

✱

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence

disclosures. Applicants have argued that they have complied, by virtue of the amendments to several claims (e.g., claims 14, 16, 19). However, a computer-readable diskette is required.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

The abstract is too long. The size of the abstract should be reduced so that it is no more than about 2/3 of a page.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have shown anticancer activity for betulinol diacetate and betulonic aldehyde. However, claim 48 is drawn to a method of using peptide and antibody conjugates of

betulinol to treat cancer. The issue, then, is whether any of the conjugates *per se* have anticancer activity, or alternatively, whether betulinol (or an active derivative thereof) is released *in vivo*. There is no evidence of either. Even if cleavage of the bond between betulinol and the peptide (or protein) can occur, there would remain the issues of proper anatomical localization, and further metabolism (e.g., by P-450) of the betulinol derivative to an inactive compound. Even undue experimentation would provide no assurance that an active compound would be released from the conjugate.

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- The "Pisha" reference ("Discovery of betulinic acid as a selective inhibitor of...") has been stricken from the IDS because no citation was provided.
- US Patent 5,399,672 was stricken from the IDS because a copy of the patent was not received.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800